



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,745	03/18/2004	Tuan Q. Tran	07860004US	5337

7590  
McGuire Woods LLP  
Suite 1800  
1750 Tysons Boulevard  
McLean, VA 22102

EXAMINER
----------

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
----------	--------------

3772

MAIL DATE	DELIVERY MODE
-----------	---------------

08/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,745	<b>Applicant(s)</b> TRAN ET AL.	
	<b>Examiner</b> NIHIR PATEL	<b>Art Unit</b> 3772	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05.21.2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12, 15, 17-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 15, 17-22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05.21.2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed on May 21<sup>st</sup>, 2008 have been fully considered but they are not persuasive. The applicant argues that walker does not disclose a connection port proximate the bottom of the hollow body configured to connect to an external nebulization chamber, the connection port comprising a nebulizer inlet and a nebulizer outlet; an air flow path having portions antiparallel to one another through an interior of the hollow body. The examiner disagrees with the applicant's arguments. Walker does disclose a connection port proximate the bottom of the hollow body (**see figure 1; the area that connects the breathalyzer chamber 10 to the container 25 is defined as a connection port**) configured to connect to an external nebulization chamber **25 (container 25 defining the nebulization chamber)**, the connection port comprising a nebulizer inlet and a nebulizer outlet; an air flow path having portions antiparallel to one another through an interior of the hollow body (**see figure 1**).

### ***Response to Amendment***

2. The amendment filed on May 21<sup>st</sup>, 2008 is acknowledged by the examiner. The amendment comprises cancellation of claims 1-11, 13, 14, 16 and 23 and amendment to claims 12, 17 and 18.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3772

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims **12, 15, 17-22, and 24-28** are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al. (US 6,679,250).

5. **As to claim 12**, Walker teaches an apparatus that comprises a hollow body (**see figure 1; the top part of the body is chamber 10; the bottom part of the hollow body is the area that connects the breathalyzer chamber 10 to the container 25 is defined as a connection port**); a connection port proximate the bottom of the hollow body (**the distribution cap is defined as the connection port**) configured to connect to an external nebulization chamber, the connection port comprising a nebulizer inlet and a nebulizer outlet (**see figure 1**); a vent **47** proximate the top of the hollow body (**see figures 1, 4a and 4b; column 5 lines 55-65**); configured to receive ambient air upon patient's inhalation; a nebulizer inlet and a nebulizer outlet proximate the bottom of the hollow body (**see column 5 lines 30-45**); a baffle at least partially disposed within the hollow body, such that the baffle **32** is a barrier and wherein the hollow body and the baffle define an airflow path having portions anti-parallel to one another through an interior of the hollow body (**see figure 1; column 5 lines 40-50**); wherein the drug delivery mouthpiece **12** is structured and arranged such that the patient's inhalation generates an air flow that allows the air flow path defined by the hollow body and the baffle to deliver a medicament to the patient (**see figure 1 and column 5 lines 1-5; 65-67 and column 6 lines 1-5**).

6. **As to claim 15**, Walker teaches an apparatus wherein the baffle includes a substantially planar member disposed between an intake flow path and a delivery flow path (**see figure 1**).

Art Unit: 3772

7. **As to claim 17**, Walker teaches an apparatus wherein the baffle is configured to protrude into the external nebulization chamber connected to the connection port (**see figure 1**).
8. **As to claim 18**, Walker teaches an apparatus wherein the baffle is configured to direct an airflow to an intake flow path out of the hollow body and into the external nebulization chamber connected to the connection port, and the baffle is configured to direct an airflow toward a delivery flow path from the external nebulization chamber connected to the connection port into the hollow body (**see figure 1**).
9. **As to claim 19**, Walker teaches an apparatus that further comprises a delivery conduit arranged proximate the top of the hollow body (**see figure 1**).
10. **As to claim 20**, Walker teaches an apparatus wherein the conduit includes an exhaust outlet **11** (**see figure 1**).
11. **As to claim 21**, Walker teaches an apparatus wherein the exhaust outlet is selectably sealable (**see figure 1**).
12. **As to claim 22**, Walker teaches an apparatus wherein the exhaust outlet includes a one-way valve (**see figure 1**).
13. **As to claim 24**, Walker teaches an apparatus that further comprises a delivery conduit arranged between the top of the hollow body and the bottom of the hollow body (**see figure 1**).
14. **As to claim 25**, Walker teaches an apparatus wherein the vent is sealably configured (**see figures 1, 4a and 4b; column 5 lines 55-65**).
15. **As to claim 26**, Walker teaches an apparatus wherein the nebulizer is configured to aerosolize a substance (**see the summary of the invention**).

Art Unit: 3772

16. **As to claim 27**, Walker teaches an apparatus wherein the substance includes medicament **(see the summary of the invention)**.

17. **As to claim 28**, Walker teaches an apparatus wherein the vent is configured to exhaust air upon the patient's exhalation. **(see figures 1, 4a and 4b; column 5 lines 55-65)**.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

Art Unit: 3772

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/  
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772